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EXAMINER	
PANI, JOHN	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
01/19/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/657,829	KRIVITSKI ET AL.	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16-22 and 28-31* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16-20 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 14 and 30 are objected to because of the following informalities: Lines 12-13 of claims 14 and 30 recite "calculating the blood flow rate as a function of less than a total volume . . . .". A function is "of a variable". As currently constructed, the claim does not appear to include a variable, but rather, an operation or range (i.e. “less than a total volume . . . .”). It is suggested to insert –a volume— prior to “less than” in order to clarify that the blood flow rate is calculated as a function of a volume that is less than a total volume. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 31 requires “further including quantifying a first amount of the indicator passing through the terminal port, and utilizing the quantified first amount in calculating the blood flow rate". Claim 14, which claim 31 depends from, requires "calculating the blood flow rate as a function of less than a total volume of the indicator passed through the indicator lumen". However, it is noted that in order to calculate the blood flow "as a

function of [a volume] less than a total volume of the indicator passed through the indicator lumen" in the manner described in the original disclosure, one *must* quantify "a first amount of the indicator passing through the terminal port", determine the portion ("a") of this amount with respect to the total amount of indicator, and multiply this portion by the total volume ("V"; see Equations 26 and 27; no other options are disclosed). The use of "further including" in claim 31 appears to require a separate step, rather than a step that is part of a previously claimed step. Because it is unclear whether claim 31 thus requires a distinct step or is part of step "(c)" of claim 14, the metes and bounds of claim 31 are indefinite.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 31 requires "further including quantifying a first amount of the indicator passing through the terminal port, and utilizing the quantified first amount in calculating the blood flow rate". The original disclosure does not support "quantifying a first amount of the indicator passing through the terminal port, and utilizing the quantified first amount in calculating the blood flow rate".

Double Patenting

7. Applicant is advised that should claim 14 or 30 be found allowable, claim 30 or 14, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,089,103 to Smith ("Smith '103").

10. Smith '103 discloses:

In reference to Claim 29

A method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port ("distal opening") of the indicator lumen; passing the indicator through the indicator lumen to

pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); sensing the indicator at a location that is proximal to the terminal port and distal to the injection port (note that the patient's body, for example the blood cells or blood vessel cells, would in some way sense the injection of indicator in the area between the most proximal side port 16 and the terminal port at the end of 14, as the indicator is a volume of cold saline); and calculating the blood flow rate based on passage of the indicator through the terminal port (col. 4 lines 20-40; note that because the transit time is used to calculate the flow rate, and the passage of indicator through the terminal port is used to determine the transit time, the blood flow rate is calculated a as a function of its passage through the terminal port).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 14, 17, 19, 20, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,089,103 to Smith ("Smith '103") US in view of Pat. No. 6,343,514 to Smith ("Smith '514").

In reference to Claims 14 and 30

Smith ‘103 discloses a method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port (“distal opening”) of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); calculating the blood flow rate (see col. 5 line 60 – col. 6 line 1). Smith ‘103 further discloses that less than a total volume of the indicator passed through the indicator lumen is injected into the blood vessel (see col. 4 lines 19-34). However, it is unclear whether Smith '103 calculates the blood flow rate as a function of less than a total volume the indicator passed through the terminal port. Smith ‘103 does however note that the flow parameter is calculated similarly to the method found in WO 97/27802, of which Smith '514 is a continuation (col. 5 lines 60-65).

Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate (see col. 7 lines 20-44). It would have been obvious to one having ordinary skill in the art at the time of the invention to have similarly used the total volume of injected indicator to determine the blood flow rate, as Smith ‘103 explicitly states that this method “is suitable for the determination of the so called Coronary Fractional Reserve (CRF)” (col. 5 lines 60-63), and Smith ‘103 uses the blood flow rate to calculate CFR.

Because Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate, and Smith '103 discloses that the total volume of injected

indicator is less than the total volume of the indicator passed through the indicator lumen, this combination renders obvious the claimed invention.

In reference to Claim 17

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses passing the indicator through the indicator lumen to contact a portion of the guide wire (col. 4 lines 34-37).

In reference to Claim 19

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses calculating the blood flow rate comprises compensating for a volume of the indicator passing through the terminal port (by using a total volume).

In reference to Claim 20

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses the calculated blood flow rate is described by a relationship $Q = (k(T_b-T_i)*V(1-a))/S$, where Q is the calculated blood flow rate, k is a coefficient related to thermal capacity of a measured flow and the indicator, T_b is a temperature of a measured flow prior to injection of the indicator, T_i is a temperature of the indicator prior to entering the measured flow, V is a volume of the indicator, S is an area under a temperature versus time curve resulting from a mixing of the indicator and a is a portion of the indicator passing through the terminal port, the calculated blood flow rate being a value provided by an appropriate selection of k, T_b, T_i, V, S, and a. (Note: This limitation has been interpreted to essentially require that for the calculated flow

value, the flow value calculated in claim 14 could be obtained by choosing appropriate values for the variables in the cited relationship. The "blood flow rate" calculated in claim 14 is essentially some numerical value, and any numerical value could be generated using the claimed relationship of claim 20 by selecting the appropriate combination of values for the parameters).

In reference to Claim 28

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses comprising sensing the indicator intermediate the terminal port and the injection port along a direction of blood flow (see Fig. 3, the sensor 4 is located intermediate the terminal port and the injection port at least in a direction orthogonal to the longitudinal axis of the catheter 14).

In reference to Claim 31

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above), and Smith '514 further includes quantifying a first amount of the indicator passing through the terminal port, and utilizing the quantified first amount in calculating the blood flow rate (note that Smith '514 quantifies the total volume of injected liquid by using it as a variable "V"; in Smith '103, "V" would include the amount of indicator passing through the terminal port, and this amount would have a determined value –i.e. be quantified- because it is part of a larger quantified value; because the larger quantified value "V" is utilized in calculating the blood flow rate, so is the amount passing through the terminal port, as this amount is a part of the larger value "V").

13. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ‘103 in view of Smith ‘514 as applied to claim 14 above, and further in view of US Pat. No. 5,221,256 to Mahurkar ("Mahurkar").

In reference to Claims 16 and 18

Smith ‘103 in view of Smith ‘514 discloses the method of claim 14 (see above) and Smith ‘103 further discloses passing the guide wire through the indicator lumen to increase a flow of the indicator through the injection port (as its presence would increase flow through these compared with a situation in which it was not there) but does not explicitly teach a reduced cross sectional area of the indicator lumen. Mahurkar teaches (see Fig. 4) a catheter with a fluid injection lumen with multiple ports (21, 22). The injection lumen tapers and has a reduced cross-sectional area at its tip. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Smith ‘103 in view of Smith '514 by making the catheter with a similar tip and lumen configuration so that the distal tip would be more flexible and atraumatic as implicitly taught by Mahurkar.

Response to Arguments

14. Applicant's arguments with respect to claims 14, 16-22, and 28-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 1/12/11

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736